FDAAA Reporting

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Applicable Clinical Trials (ACT's) that Require Reporting

- Review compliance report
- Contact principal investigator, research nurse, and/or statistician via email
  - Request manuscript
  - Provide CT.gov basic results data element definitions
  - Meet with investigator/research nurse (optional)
- Contact data management for FDAAA report (e.g., age, gender, adverse events…)

Data Entry

- Edit current data in CT.gov (i.e. expand acronyms)
- Input data from manuscript, FDAAA reports and/or statistician report
- Contact principal investigator, research nurse, and/or statistician for clarification re: manuscript… if needed

Data Review and Completion

- Email PDF copy of the data to the principal investigator, research nurse, and/or statistician with questions
- Principal investigator, research nurse, and/or statistician respond via email
  - Cycle is repeated until all data issues are resolved via email or teleconference
  - PI approves final version
- Data is completed

CT.gov Helpful Features

- Adverse event download/upload
  - Easy to upload hundreds of AE's quickly
- Problems Report
  - Identify studies that require action (e.g., update study status)
- "What's New"
  - Review database updates

Lessons Learned

- Patience, flexibility, and time management is key
  - Tedious
  - Juggle multiple studies

Contact Information

- NCI, CCR, FDAAA Database Administrator:
  - Lisa King: 301-451-6646 or kingl@mail.nih.gov
- NCI Protocol Support Office
  - nciprotocolsupportoffice@mail.nih.gov